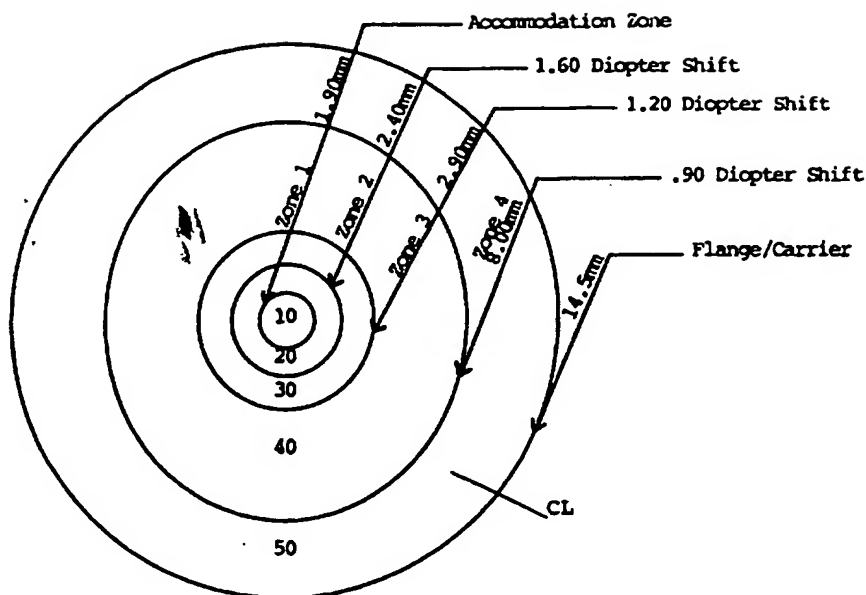




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| (71)(72) Applicant and Inventor: DUNN, Stephen, A. [US/US];<br>1949 Naniu Place, Honolulu, HI 96822 (US). |  |  |   |
| (74) Agent: HSIA, Martin, E.; P.O. Box 939, Honolulu, HI 96808 (US).                                      |  |  |   |
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(54) Title: CONTACT LENS AND PROCESS FOR FITTING



## (57) Abstract

A contact lens with a central region (10) that is optimally less than approximately 1.9 millimeters in diameter and that is preferably overcorrected by approximately 25 % to 100 % over the correction needed for reading. Unexpectedly, the central region (10) does not impair distance vision, but compensates for presbyopia and therefore allows a user to focus on objects within a range of near and intermediate distances. A method for fitting the contact lens is also provided.

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DESCRIPTIONContact Lens and Process for Fitting  
Technical Field.

5           This invention relates to a contact lens that restores the ability to focus on objects within a range of distances near to the user (referred to as "natural accommodation"), while retaining the ability to see distant objects. More specifically, this invention  
10 relates to a contact lens with a conventional spherical concave surface conforming to the curvature of the eye (base curve) and having a non-conventional convex surface (optic curve) combining spherical and non constant aspherical curvature resulting in an optical  
15 system that provides true monocular presbyopic correction (correction of presbyopia in each eye independently, instead of partial or full distance correction in one eye and partial or full near correction in the other) and restores the phenomenon of  
20 "natural accommodation." Additionally, the invention affords a methodology of fitting that substantially reduces the skill and experience required by the contact lens fitter to a very basic level while affording a high degree of clinical success and patient satisfaction.

25           Normally between the ages of 40 and 45, presbyopia or old sightlessness is brought about by loss of elasticity of the crystalline lens of the eye, causing blurred vision at near points due to the reduction of the ability of the eye's natural lens to  
30 accommodate the changes in curvature necessary to focus on both near and distant objects.

          When a person is free of presbyopia, the eye retains its full range of natural accommodation. This type of person's vision can be corrected by eyeglasses  
35 or contact lenses providing only the correction required for distance vision, and natural accommodation would automatically provide correction for near and

1 intermediate distance vision.

Background Art.

For the contact lens wearer who requires presbyopic (or near vision) correction, in addition to  
5 distance correction, a variety of options have been available. These individuals may be fitted with single vision contact lenses corrected for distance, and wear reading glasses for near correction. Another  
10 alternative is to provide a contact lens for one eye that is corrected for distance vision and to provide a contact lens for the other eye that is corrected for near vision (this practice is referred to as monovision because only one eye is corrected for near vision), or the fitting of bifocal or multifocal contact lenses.

15 During the 1950's, a variety of contact lenses were designed for the correction of presbyopia. These contact lenses, although very innovative in design, met with only limited success because the only readily  
20 available material was Poly Methyl Methacrylate (Plexiglass), also known as PMMA, which does not transmit oxygen. As bifocal and multifocal designs of the period were quite thick and heavy compared to conventional distance correction contact lenses, these presbyopic contact lenses were uncomfortable to wear for  
25 substantial periods of time. Additionally, the fitting of these bifocal and multifocal contact lenses required considerable time and skill on the part of the contact lens fitter.

During the 1970's, both soft contact lenses and  
30 rigid gas permeable (RGP) contact lenses were introduced. With the availability of these new materials, renewed enthusiasm brought about several new designs for contact lenses for the correction of presbyopia.

35 RGP materials provide oxygen transmission through the lens material itself, and afforded new hope for the earlier designs developed in PMMA material.

1 However, lens thickness and resultant patient discomfort continued to be a problem.

One of the early benefits recognized with soft contact lenses was the comfort and ease of fitting and, for this reason, by 1995 approximately 85% of new contact lens wearers are being fitted with soft contact lenses. As soft contact lenses command such a large share of the contact lens market, it is natural that considerable effort would be made to develop bifocal and multifocal contact lens designs in soft contact lens material.

There are two types of contact lens designs for the correction of presbyopia -- Alternating (or Translating) and Simultaneous.

15 (1) In the alternating (or translating) vision technique, the lenses are very similar in design to bifocal eyeglass lenses in that the wearer sees through the distance segment in the upper portion of the lens when looking straight ahead and sees through a lower near vision segment when the eye (moves) to look down. Alternating vision lenses have proven to be successful in RGP designs, but have met with little success when designed in soft contact lenses.

Perhaps the reason that alternating vision soft contact lens designs were not as successful as the same design concept in RGP materials was because lens translation is necessary for this design to be successful. The translation from distance to near is achieved through the mechanical action of the lens resting on the lower eyelid and, when the eye looks down, the lens remains stable on the lower eyelid causing the pupil of the eye to translate from the distant vision portion of the lens to the near vision portion of the lens. Soft lens material by its nature caused this modality to fail as there was insufficient rigidity in the soft lens to remain properly positioned

1 on the lower eyelid and often the lens would slip  
underneath the lower eyelid during translation.

(2) Simultaneous vision bifocal or multifocal  
contact lenses are either concentric or aspheric in  
5 design with focal power changing through different areas  
of the lens. Lenses are fitted so that distance,  
intermediate and near zones focus images simultaneously  
on the retina of the eye and the brain then separates  
out the image desired.

10 Theoretically, with adaptation, the ability to  
change focus naturally from near to far with no blurring  
in between can be achieved with simultaneous vision  
lenses in both RGP and soft contact lenses.

As alternating presbyopic designs proved to be  
15 unsuccessful in soft contact lens designs, most of the  
development work with soft contact lenses was done in  
the area of simultaneous presbyopic correction with  
concentric designs or aspheric designs.

During the 1980's, several designs of  
20 concentric and aspheric soft contact lenses were  
introduced. Soft aspheric multifocal contact lenses  
typically provided relatively weak reading addition  
power and therefore worked best in early presbyopia.

Reading addition powers are referred to by eye  
25 care professionals as "add" power, and represent the  
difference between the distance correction and near  
correction prescribed by an eye care professional for  
eyeglasses or contact lenses. Accordingly, a  
prescription of "-3 with a +2 add" (which would be  
30 typical for moderate presbyopia) would mean that  
distance vision requires -3 diopters of correction, and  
near vision requires an additional 2 diopters of plus  
correction, resulting in -1 diopters of near vision  
correction. In conventional monovision, the dominant  
35 eye would be fitted with a -3 distance correction lens,  
and the other eye would be fitted with a -1 near  
correction lens.

1           This type of solution is often satisfactory in  
early presbyopia because the user still has some  
remaining visual accommodation and the needed add power  
is usually between +.75 and +1.25, which is usually low  
5 enough for the brain to comfortably select the desired  
image in most people. However, conventional monovision  
becomes less satisfactory as presbyopia becomes more  
advanced because the needed add power increases and  
visual accommodation has deteriorated further, so that  
10 the visual imbalance exceeds the brain's ability to  
select the desired image from the appropriate eye.

Typically, early presbyopes, would be between  
the age of 40 and 45, and would require add power of  
between +1.00 and +1.50 diopters. Moderate presbyopes  
15 would usually be between 45 and 55 years and would  
require add power of between +1.50 and +2.00 diopters.  
Mature presbyopes would usually be older than age 55 and  
require an add power of between +2.00 and +3.00 diopter.

The add corrective power of current aspheric  
20 multifocal contact lens designs is usually limited to  
only +.75 to +1.25 diopters because the brain must be  
able to separate out the desired image (and also  
suppress the undesired images) from the multiple images  
(near, intermediate or distant) being simultaneously  
25 focused by the multifocal contact lens design. In order  
to achieve this suppression, the images cannot be too  
different from each other. However, if aspheric  
corrections are increased in attempts to achieve higher  
add powers, the images become too different for the  
30 brain to suppress the undesired images, resulting in  
blurred vision. Even at add powers of +.75 to +1.25  
diopters, many patients suffer some blurring or ghosting  
with multifocal contact lens designs because their  
brains are not able to completely separate the desired  
35 image while simultaneously completely suppressing the  
undesired images.

1           Some contact lens fitters may attempt to use  
aspheric designs to achieve near distance correction of  
up to +2.00 diopters (or more) by undercorrecting the  
distance vision of the non-dominant eye by between .25  
5 and 1.00 diopters, thereby theoretically providing up to  
+2.00 diopters (or more) of near vision correction,  
instead of the +.75 to +1.25 diopter correction that  
would be provided if that eye had been fully corrected  
for distance vision with an aspheric multifocal contact  
10 lens. The dominant eye would be corrected to maximum  
distance acuity in such a situation. However, this  
creates even more blurring and ghosting. This technique  
is called modified monovision.

Aspheric optics have been incorporated on both  
15 the front and back surfaces of soft contact lenses.  
However, it is believed that front surface aspherical  
multifocal soft contact lenses provide better presbyopic  
correction. Still, only limited success is achieved  
because providing add power of +.75 to +1.25 (or more)  
20 usually results in reduced distance acuity. For this  
reason, many contact lens fitters find it necessary,  
when using aspheric soft multifocal contact lenses, to  
undercorrect the distance power in one eye to improve  
near vision, while correcting the other eye fully for  
25 distance vision, as discussed above. When attempting to  
fit moderate to mature presbyopes, this modified  
monovision almost always results in a visual compromise  
similar to that of conventional monovision.

Concentric multifocal lens designs have an  
30 advantage over aspheric designs in the fitting and  
correcting of more mature presbyopes requiring add power  
of more than +1.25 diopters, primarily due to the  
availability of higher add power correction and central  
power zones of different diameters. Concentric soft  
35 multifocal contact lenses have been made with the  
central distant correction zones and central near  
correction zones. In the latter designs, the central

1 power zones would be corrected by the amount prescribed  
to correct near vision. It is believed that central  
near add zones have been more successful at correcting  
presbyopia than central distance zones, when  
5 incorporated in concentric multifocal soft lens designs.  
Although concentric center add multifocal designs have  
the ability to correct higher add power requirements,  
most individuals fitted with this type of lens  
experience moderate to significant amounts of visual  
10 discomfort due to ghosting of images or a 3-D effect, at  
near distances. These effects diminish with adaptation,  
but still cause a high portion of wearers to discontinue  
the use of this type of presbyopic contact lens.

The reality of the existing art of presbyopic  
15 correction with simultaneous vision contact lenses is  
that no currently available lens system, be it aspheric  
or concentric, provides monocular multifocal correction  
for moderate to mature presbyopia. In most cases, some  
form of modified monovision is required in an attempt to  
20 satisfy the visual requirement for near and far vision.  
To this end almost all currently available presbyopic  
contact lens manufacturers indicate in their fitting  
manuals the requirement of compensating one eye more for  
near and the other eye more for distance correction.  
25 This is the norm rather than the exception.  
Additionally, no currently available multifocal contact  
lens has the ability to restore the phenomena of natural  
accommodation and successful results are difficult to  
achieve and require considerable time and experience on  
30 the part of the fitter.

It is therefore an object of this invention to  
provide true multifocal correction for moderate and  
mature presbyopes requiring up to +3.00 diopters of add  
power without the need to compensate one eye for near  
35 and the other eye for distance.

1           It is a further object of this invention to  
provide rapid patient adaptation with minimal initial  
visual discomfort.

          It is a still further object of this invention  
5 to provide a presbyopic optical system that restores the  
phenomenon of natural accommodation.

          It is a still further object of this invention  
to provide a system of fitting and methodology that  
allows a contact lens fitter with little or no  
10 multifocal contact lens fitting experience to achieve a  
very high degree of success and patient satisfaction.

Disclosure of Invention

          These and other objects are achieved by a  
contact lens having a central circular region (an  
15 "accommodation zone" or "sweet spot" named zone 1) that  
is overcorrected for near vision, and that is small  
enough that it does not impair distance vision.  
Preferably, a plurality of concentric transition regions  
(or rings), optimally two (named zone 2 and zone 3,  
20 progressing radially outwardly), are provided between  
the sweet spot and the outer region (or ring) of the  
lens (named zone 4), which is corrected for distance  
vision. Preferably, the sweet spot has a diameter of  
between approximately 1.0 millimeters and approximately  
25 2.5 millimeters, preferably between approximately 1.5  
millimeters and approximately 1.9 millimeters, and  
optimally either approximately 1.5 millimeters or  
approximately 1.9 millimeters. Preferably, the  
transition rings (zones 2 and 3) are each approximately  
30 .5 millimeters wide. Preferably also, the remaining  
portion of the lens (zone 4) extends radially outward  
from the outermost transition ring to at least  
approximately 8 millimeters. Because the human pupil  
cannot expand beyond approximately 8 millimeters in  
35 diameter, the portion of the lens extending more than  
approximately 8 millimeters radially outward from the

1 center is not an optical portion and functions only as a carrier.

Preferably, the sweet spot is spherical and is overcorrected by between 25% and 100% over the near vision correction prescribed for the user. Preferably, the remaining optical portions of the lens are aspheric, with different diopter shifts over different regions. Optimally, for high add power, zone 2 provides a diopter shift of approximately 1.6 diopters, zone 3 provides a diopter shift of approximately 1.2 diopters, and zone 4 provides a diopter shift of approximately .9 diopters. For low add power, optimally zone 2 provides a diopter shift of approximately 1.1 diopters, zone 3 provides a diopter shift of approximately .8 diopters, and zone 4 provides a diopter shift of approximately .6 diopters.

The contact lens manufacturing lathe disclosed in the example below provided contact lenses that achieved the desired results. However, some experimentation may be necessary to achieve the desired result with different equipment, but this experimentation should not be undue.

The invention incorporates both concentric and aspheric design principles and can be produced with a high add power correction or a low add power correction. In addition, the lens system offers two accommodation zone diameters for different sized pupils to achieve maximum near point acuity without reduction in distance visual acuity.

The higher add power lens has a power transition of 3.7 diopters across the usable optic zone, and the low add power lens has a power transition of 2.6 diopters across the usable optic zone.

The accommodation zone should cover approximately 50% of the pupil area for maximum success in distant, intermediate and near visual acuity. The accommodation zone functions to restore the phenomenon of natural accommodation by creating a very small area

1 of over magnification in the center of the pupil of  
approximately 25% to 100% over the near vision  
correction required by the indicated reading add power.  
Surprisingly, distance vision will not be substantially  
5 impaired if the accommodation zone covers 50% or less of  
the pupil area. Further, the function of natural  
accommodation will be restored to an unexpectedly great  
extent.

Although the inventor is not sure (and the  
10 validity and enforceability of any patent issuing hereon  
shall not be affected by the accuracy or inaccuracy of  
this explanation), the inventor believes that, in near  
vision, a user's pupils constrict, so that the  
accommodation zone occupies a large enough portion of  
15 the pupil area for the accommodation zone to become  
effective. Normal reading correction is prescribed for  
approximately 15 inches (approximately 38 centimeters).  
Accordingly, the overcorrection of the accommodation  
zone (sweet spot) allows the user to see from 8 inches  
20 to 15 inches, thus restoring the function of natural  
accommodation. In distance vision, however, the pupil  
will be normally dilated, so that the accommodation zone  
is small enough that the brain ignores the image  
generated by it. The constriction of the pupil for near  
25 vision is known as "accommodative pupil response."

The accommodation zone is blended to the  
distance zone 4 via two zones of non constant  
aspherocity which allows true monocular correction of  
near, intermediate and distant vision. Near vision  
30 correction, when tested at the standard distance of  
approximately 15 inches (approximately 38 centimeters)  
offers normal best corrected acuity and when reading  
material is brought closer to the eyes, up to about  
eight inches (approximately 20 centimeters), near acuity  
35 remains stable and often improves due to the increased  
near power created by the sweet spot.

1           Due to the non constant aspheric transition  
from the sweet spot to zone 4, adaptation problems  
associated with prior designs of concentric or aspheric  
multifocal contact lenses are substantially reduced or  
5           eliminated completely.

          Historically, the fitting of multifocal contact  
lenses has been more an art than a science as the  
variables associated with fitting presbyopic contact  
lenses are considerable. Often success has only been  
10          achieved through the process of trying many different  
lenses on the patient in the hope of finding a lens that  
generates a good presbyopic response. The contact lens  
fitter's degree of experience in the fitting of  
multifocal lenses has also been a key to achieving a  
15          successful fitting with good visual results.

          The fitting of lenses according to this  
invention requires accurate centering of the lens over  
the pupil of the eye in order to achieve the expected  
results. To determine the location of the sweet spot  
20          relative to the pupil is often difficult because the  
pupil may not be aligned with the center of the cornea  
or for other reasons. Thus, the invention also  
incorporates the use of a diagnostic trial lens with a  
white ring corresponding in diameter and location to the  
25          sweet spot. The exact position of the center of the  
contact lens can be determined and the relative position  
of the sweet spot to the pupil and the percentage of  
pupil covered by the sweet spot is easily observed. The  
use of the diagnostic lens allows the fitter to very  
30          quickly determine the proper sweet spot size, which  
increases the chances of successful fitting. For  
example, if the accommodation zone does not align within  
the pupil, the fitter knows that the standard lens  
design will not work and a custom lens design with an  
35          offset accommodation zone will be required.

          Other objects, features and advantages of the  
present invention will become more fully apparent from

1 the following detailed description of the presently preferred embodiments for carrying out the invention and the accompanying drawings.

Brief Description of Drawings.

5 Fig. 1 is a top elevational schematic view of a presently preferred embodiment of a contact lens according to the present invention for a person who needs a high degree of reading correction (high add power) and a larger sweet spot;

10 Fig. 2 is a top elevational schematic view of a presently preferred embodiment of a contact lens according to the present invention for a person who needs a high degree of reading correction (high add power) but a smaller sweet spot;

15 Fig. 3 is a top elevational view of a contact lens according to the present invention for a person who needs a lesser degree of reading correction (low add power) and a larger sweet spot; and

20 Fig. 4 is a top elevational view of a contact lens according to the present invention for a person who needs a lesser degree of reading correction (low add power) and a smaller sweet spot.

Best Modes for Carrying Out Invention.

25 The presently preferred best modes for carrying out the present invention are illustrated by way of example in Figs. 1 to 4.

Referring to Fig. 1, shown is a first preferred embodiment of a contact lens CL according to the present invention. The contact lens CL is divided into a  
30 central circular region and four concentric ring shaped regions. The central region 10 will be referred to as zone 1, the accommodation zone, or the sweet spot. The immediately adjacent first ring shaped region 20 will be referred to as zone 2. The second ring shaped region 30 immediately adjacent to zone 2 will be referred to as zone 3. The third ring shaped region 40 immediately adjacent to zone 3 will be referred to as zone 4.

1           The maximum diameter of a human pupil when it  
is fully dilated is approximately 8 millimeters, so that  
the ring shaped region 50 of the contact lens extending  
radially outwardly from zone 4 is not an optical  
5 surface, but merely functions as a carrier to maintain  
the optical surface of zones 1 through 4 in position.

Structurally, the zones can be described as  
follows. Zone 1 is preferably approximately 1.5 to 1.9  
millimeters in diameter. Zone 2 and zone 3 are both  
10 preferably approximately .5 millimeters in width. Zone  
4 preferably extends outwardly from a radius of  
approximately 2.5 millimeters to approximately 2.9  
millimeters to approximately 8 millimeters. Thus, the  
lens can be described as having a central sweet spot  
15 (zone 1), two .5 millimeter intermediate zones (zones 2  
and 3), and a distance zone (zone 4) extending outwardly  
from the intermediate zones to the edge of the optical  
portion of the contact lens (approximately 8 millimeters  
radially outwards from the center). The total diameter  
20 of the contact lens CL will be approximately 13 to  
approximately 16 millimeters for a soft contact lens, so  
that the carrier 50 will normally extend from  
approximately 8 millimeters outwards to approximately  
13.5 millimeters to approximately 15.0 millimeters, and  
25 optimally 14.5 millimeters.

If this invention is practiced in connection  
with a hard contact or RGP lens, the total diameter of  
the contact lens CL would be between approximately 7.0  
millimeters and approximately 11.0 millimeters, and  
30 typically between approximately 8.0 millimeters and  
approximately 10.5 millimeters, and optimally  
approximately 9.5 millimeters.

Zone 1, the sweet spot, is preferably  
spherical, although it can be aspherical. Zones 2, 3  
35 and 4 are preferably aspherical in order to accommodate  
transitions in corrective power across these zones.

1           Conventional contact lenses consist of a  
carrier with a central lens portion. The central lens  
portion is usually corrected for distance vision. This  
is described in U.S. Patent 4, 119, 2312, Evans, which  
5 is hereby incorporated by reference.

The present invention differs from conventional  
multifocal contact lenses in that a small central  
portion of the lens is overcorrected beyond the  
correction that would be necessary for reading. This  
10 central portion, the sweet spot or accommodation zone,  
is small enough so that, surprisingly, it does not  
impair distance vision when the user is looking at  
distant objects, but it restores the ability to focus on  
near objects within a substantial range of distances  
15 from the wearer, such as, between 8 inches and 15  
inches. It is believed that the transition zones  
restore the ability to focus as follows: zone 2  
restores the intermediate visual acuity between  
approximately 15 inches and approximately 36 inches, and  
20 zone 3 restores the intermediate visual acuity between  
approximately 36 inches and full distance correction  
(infinity).

In determining the appropriate curvatures for  
the various zones in the contact lens CL, the correction  
25 to restore distance vision must be determined first.  
The distance power correction is then applied to zone 4.  
The distance power correction is usually within a range  
between +20.00 diopters to -20.00 diopters.

After the distance correction is determined,  
30 the amount of correction for near vision ("add power")  
should be calculated. A person with early to moderate  
presbyopia would be prescribed a low additional reading  
power of up to +1.75 diopters (referred to as a "low  
add"). A moderate to advanced presbyope would require a  
35 reading correction from 1.75 to 2.75 diopters (referred  
to as a "high add").

1           For a high add presbyope, the aggregate change  
in powers across the various zones is preferably  
approximately 3.7 diopters. For a low add presbyope,  
the aggregate change in powers across the various zones  
5 is preferably approximately 2.6 diopters (approximately  
70% of the total diopter shift for a high add).

The corrective power of the various zones  
preferably does not remain constant within each zone.  
Instead, for a high add presbyope, it is preferred that  
10 there be as 1.6 diopter shift across zone 2, a 1.2  
diopter shift across zone 3 and a .9 diopter shift  
across zone 4, so that the total diopter shift across  
zones 2, 3, and 4 is 3.7 diopters.

Because the sweet spot is so small, and because  
15 it must be centered in the pupil in order for the  
invention to function properly, the contact lens CL must  
be precisely manufactured in order to be sure the sweet  
spot is properly centered over the center of the pupil.  
In order to accomplish this critical centering, it is  
20 preferred to mark a 1.9 millimeter centered spot,  
preferably white, on a pair of trial diagnostic contact  
lenses. With such a pair of trial diagnostic contact  
lenses, it is possible to detect whether a user's pupil  
is off center (and other problems), so that the contact  
25 lens of the present invention can be properly  
manufactured to center the sweet spot over the pupil.

The inventor has discovered that an  
overcorrected central portion of between approximately 1  
to approximately 2.5 millimeters, and preferably  
30 approximately 1.5 to approximately 1.9 millimeters  
(optimally either 1.5 millimeters or 1.9 millimeters) in  
diameter does not substantially impair distance vision  
of a contact lens. Surprisingly, the inventor also has  
discovered that overcorrecting the central portion  
35 beyond the correction needed for near vision, restores  
an unexpectedly large portion of the function of natural

1 accommodation of the eye so that focus can be achieved  
over a range of near distances.

Although, other contact lenses are known with  
central areas that are differently corrected than  
5 distance portions, those central segments are either  
larger than the present invention's "sweet spot," or  
they do not overcorrect the sweet spot, or both.

It is preferred that the various zones have  
constant widths even if the size of the sweet spot  
10 differs. Thus, if the sweet spot is 1.9 millimeters in  
diameter, the diameters of zones 2, 3, and 4 would all  
be approximately .4 millimeters greater than the  
corresponding diameters in a lens with a 1.5 millimeter  
diameter sweet spot. It is also preferred that the  
15 diopter shifts between zones 2, 3, and 4 remain constant  
regardless of the size of the sweet spot for  
mature presbyopes. Fig. 2 shows a contact lens  
according to the present invention with a smaller sweet  
spot.

20 For early presbyopia, the amounts of the  
diopter shifts across zones 2, 3, and 4 are preferably  
approximately 70% of the diopter shifts for mature  
presbyopes. Thus, the preferred aggregate diopter shift  
for early presbyopes is approximately 70% of the diopter  
25 shifts for mature presbyopes. Thus, the aggregate  
diopter shift across zones 2, 3, and 4 would be  
approximately 2.6 diopters; the diopter shift across  
zone 2 will be approximately 1.1 diopters; the diopter  
shift across zone 3 would be approximately .8 diopters  
30 and the diopter shift across zone 4 would be  
approximately .6 diopters. Figs. 3 and 4 show contact  
lenses for early presbyopes with large and small sweet  
spots.

Although it is presently preferred to have  
35 intermediate zone 2 and 3, it is not known whether the  
presence of such zones is critical to the invention.  
Further, it is not known whether the manner in which the

1 diopter shift is achieved by the aspheric shape of the  
various zones is critical. At present, it is preferred  
that the diopter shift take place at a constant radial  
rate in each zone, so that there is a different constant  
5 diopter shift rate in each of zones 2, 3, and 4.  
However, it is also possible that the benefits of this  
invention may be achievable by using varying diopter  
shift rates within a zone, or to increase or decrease  
the number of zones.

10 Further, it is not believed to be critical that  
the diopter shifts be effected by shaping the contact  
lens. For example, it is possible to achieve the  
diopter shift by using material with differing indices  
of refraction in various different portions of the lens.  
15 Indeed, with appropriate control over the diffusion of  
materials with different indices of refraction during  
molding of contact lenses, it is possible that the  
present invention could be practiced with a lens that is  
spherical or that does not have differently formed lens  
20 portions.

The sweet spot is preferably overcorrected  
between 25% and approximately 100% stronger than the  
prescribed reading correction requirement.

For example, for a high add, it would be  
25 preferred that the sweet spot be from 3.5 to 5 diopters  
more plus add power than the distance zone (zone 4),  
between 3.5 to approximately 3.9 diopters being even  
more preferred, and approximately 3.7 diopters being  
optimal. For a low add, it would be preferred that the  
30 sweet spot be from 2.0 to 3.5 diopters more plus add  
power than the distance zone (zone 4), with between  
approximately 2.4 and approximately 2.8 diopters being  
more preferred, and optimally approximately 2.6  
diopters.

35

1

## EXAMPLE 1

A Microturn 9000 three axis radius lathe with aspheric surface cutting capabilities has been used to make contact lenses according to the present invention with base curves of 8.6 millimeters wet (6.6 millimeters dry). The lenses were manufactured dry from Ocufilecon B (a 53% water content material) and were hydrated afterwards. Therefore compensating calculations were made to achieve the appropriate hydrated parameters, such as base curve, radial expansion, linear expansion, power changes due to changes in index of refraction caused by hydration. When hydrating Ocufilecon B, the linear expansion parameter is approximately 1.35, the radial expansion parameter is approximately 1.30, and the power change parameter is approximately .57. The settings for the various radii of curvature in the various zones (for dry manufacturing using Ocufilecon B) are shown in the following cutting charts:

20

8.60 high add minus power

25

|          | Zone 1 | 2    | 3    | 4    | DIA. | C.T. | DIST. |
|----------|--------|------|------|------|------|------|-------|
| CENTER   | 1.10   | 1.50 | 1.90 | 6.00 | DIA. | C.T. | POWER |
| POWER    | 1.40   | 1.80 | 2.20 | 6.00 | DIA. | C.T. | POWER |
| pl       | 6.73   | 6.98 | 7.17 | 7.30 |      | .16  |       |
| -.25     | 6.77   | 7.02 | 7.21 | 7.35 |      | .16  |       |
| -.50     | 6.83   | 7.06 | 7.25 | 7.40 |      | .16  |       |
| -.75     | 6.86   | 7.11 | 7.29 | 7.46 |      | .16  |       |
| 30 -1.00 | 6.90   | 7.15 | 7.33 | 7.50 |      | .16  |       |
| -1.25    | 6.93   | 7.18 | 7.37 | 7.53 |      | .16  |       |
| -1.50    | 6.96   | 7.22 | 7.41 | 7.58 |      | .16  |       |
| -1.75    | 7.00   | 7.25 | 7.45 | 7.62 |      | .16  |       |
| -2.00    | 7.05   | 7.29 | 7.49 | 7.66 |      | .15  |       |
| 35 -2.25 | 7.09   | 7.33 | 7.53 | 7.70 |      | .15  |       |
| -2.50    | 7.13   | 7.37 | 7.58 | 7.75 |      | .15  |       |
| -2.75    | 7.17   | 7.41 | 4.62 | 7.79 |      | .15  |       |

|   |       |      |      |      |      |     |
|---|-------|------|------|------|------|-----|
| 1 | -3.00 | 7.21 | 7.46 | 7.67 | 7.84 | .14 |
|   | -3.25 | 7.24 | 7.51 | 7.71 | 7.89 | .14 |
|   | -3.50 | 7.28 | 7.56 | 7.76 | 7.94 | .14 |
|   | -3.75 | 7.31 | 7.60 | 7.80 | 7.99 | .14 |
| 5 | -4.00 | 7.35 | 7.65 | 7.85 | 8.04 | .13 |
|   | -4.25 | 7.38 | 7.70 | 7.90 | 8.07 | .13 |

8.60 high add plus power

10

|        | Zone 1 | 2    | 3    | 4    | DIA. | C.T. | DIST. |
|--------|--------|------|------|------|------|------|-------|
| CENTER | 1.10   | 1.50 | 1.90 | 6.00 | DIA. | C.T. | POWER |
| POWER  | 1.40   | 1.80 | 2.20 | 6.00 | DIA. | C.T. | POWER |

|    |       |      |      |      |      |     |
|----|-------|------|------|------|------|-----|
| 15 | p1    | 6.73 | 6.98 | 7.17 | 7.30 | .16 |
|    | +.25  | 6.71 | 6.95 | 7.13 | 7.27 | .17 |
|    | +.50  | 6.68 | 6.91 | 7.09 | 7.23 | .17 |
|    | +.75  | 6.65 | 6.87 | 7.05 | 7.19 | .17 |
|    | +1.00 | 6.62 | 6.84 | 7.02 | 7.16 | .17 |
| 20 | +1.25 | 6.59 | 6.80 | 6.98 | 7.12 | .17 |
|    | +1.50 | 6.56 | 6.77 | 6.94 | 7.08 | .17 |
|    | +1.75 | 6.52 | 6.73 | 6.90 | 7.04 | .18 |
|    | +2.00 | 6.49 | 6.70 | 6.87 | 7.00 | .18 |
|    | +2.25 | 6.46 | 6.66 | 6.83 | 6.96 | .18 |
| 25 | +2.50 | 6.44 | 6.63 | 6.80 | 6.93 | .18 |
|    | +2.75 | 6.40 | 6.59 | 6.76 | 6.89 | .18 |
|    | +3.00 | 6.37 | 6.56 | 6.72 | 6.85 | .19 |
|    | +3.25 | 6.34 | 6.53 | 6.69 | 6.80 | .19 |
|    | +3.50 | 6.31 | 6.50 | 6.66 | 6.75 | .19 |
| 30 | +3.75 | 6.28 | 6.47 | 6.62 | 6.73 | .20 |
|    | +4.00 | 6.26 | 6.44 | 6.59 | 6.70 | .20 |
|    | +4.25 | 6.23 | 6.41 | 6.56 | 6.67 | .20 |

8.60 low add plus power

35

|        | Zone 1 | 2    | 3    | 4    | DIA. | C.T. | DIST. |
|--------|--------|------|------|------|------|------|-------|
| CENTER | 1.10   | 1.50 | 1.90 | 6.00 | DIA. | C.T. | POWER |
| POWER  | 1.40   | 1.80 | 2.20 | 6.00 | DIA. | C.T. | POWER |

|    |       |      |      |      |      |     |
|----|-------|------|------|------|------|-----|
| 1  | p1    | 6.73 | 6.93 | 7.06 | 7.17 | .16 |
|    | +.25  | 6.70 | 6.89 | 7.02 | 7.13 | .17 |
|    | +.50  | 6.67 | 6.85 | 6.98 | 7.10 | .17 |
|    | +.75  | 6.63 | 6.82 | 6.93 | 7.06 | .17 |
| 5  | +1.00 | 6.60 | 6.79 | 6.89 | 7.02 | .17 |
|    | +1.25 | 6.58 | 6.74 | 6.86 | 6.98 | .17 |
|    | +1.50 | 6.56 | 6.70 | 6.84 | 6.95 | .17 |
|    | +1.75 | 6.52 | 6.67 | 6.80 | 6.91 | .17 |
|    | +2.00 | 6.49 | 6.64 | 6.77 | 6.87 | .18 |
| 10 | +2.25 | 6.46 | 6.61 | 6.73 | 6.83 | .18 |
|    | +2.50 | 6.43 | 6.58 | 6.70 | 6.79 | .18 |
|    | +2.75 | 6.40 | 6.55 | 6.66 | 6.75 | .18 |
|    | +3.00 | 6.37 | 6.52 | 6.63 | 6.72 | .19 |
|    | +3.25 | 6.34 | 6.48 | 6.60 | 6.68 | .19 |
| 15 | +3.50 | 6.31 | 6.45 | 6.57 | 6.65 | .20 |
|    | +3.75 | 6.28 | 6.42 | 6.54 | 6.62 | .20 |
|    | +4.00 | 6.26 | 6.39 | 6.51 | 6.59 | .20 |
|    | +4.25 | 6.23 | 6.36 | 6.47 | 6.56 | .20 |

20

8.60 low add minus power

|    | Zone 1 | 2    | 3    | 4    | DIA. | C.T. | DIST. |
|----|--------|------|------|------|------|------|-------|
|    | CENTER | 1.10 | 1.50 | 1.90 | 6.00 | DIA. | C.T.  |
|    | POWER  | 1.40 | 1.80 | 2.20 | 6.00 | DIA. | POWER |
| 25 | p1     | 6.73 | 6.93 | 7.06 | 7.17 | .16  |       |
|    | -.25   | 6.77 | 6.96 | 7.10 | 7.21 | .16  |       |
|    | -.50   | 6.81 | 7.00 | 7.14 | 7.25 | .16  |       |
|    | -.75   | 6.85 | 7.03 | 7.18 | 7.29 | .16  |       |
| 30 | -1.00  | 6.89 | 7.07 | 7.22 | 7.33 | .16  |       |
|    | -1.25  | 6.93 | 7.11 | 7.25 | 7.37 | .16  |       |
|    | -1.50  | 6.97 | 7.15 | 7.29 | 7.41 | .16  |       |
|    | -1.75  | 7.01 | 7.19 | 7.33 | 7.45 | .16  |       |
|    | -2.00  | 7.05 | 7.24 | 7.37 | 7.50 | .15  |       |
| 35 | -2.25  | 7.08 | 7.28 | 7.41 | 7.54 | .15  |       |
|    | -2.50  | 7.12 | 7.32 | 7.46 | 7.58 | .15  |       |
|    | -2.75  | 7.16 | 7.36 | 7.51 | 7.62 | .15  |       |

|   |       |      |      |      |      |     |
|---|-------|------|------|------|------|-----|
| 1 | -3.00 | 7.20 | 7.40 | 7.55 | 7.67 | .14 |
|   | -3.25 | 7.23 | 7.44 | 7.59 | 7.71 | .14 |
|   | -3.50 | 7.27 | 7.48 | 7.64 | 7.76 | .14 |
|   | -3.75 | 7.31 | 7.52 | 7.68 | 7.80 | .14 |
| 5 | -4.00 | 7.35 | 7.57 | 7.73 | 7.85 | .13 |
|   | -4.25 | 7.39 | 7.61 | 7.77 | 7.89 | .13 |

It is preferred that the contact lenses conform to industry standards for inside radii, which for soft contact lenses are presently between 7.5 and 9.5 millimeters, and typically between 8.30 millimeters and 8.6 millimeters. For RGP and hard lenses, the industry standard inside radii are between 7.0 millimeters and 8.5 millimeters, and typically between 7.3 and 8.2 millimeters.

It is presently preferred that the contact lens of the present invention comprise conventional soft contact lens material, such as Ocufilecon B with 53% water content, because contact lenses have been successfully manufactured using this material. However, any conventional soft or rigid contact lens material may be used to practice the invention (as long as appropriate compensations are made for parameters that may change during hydration for soft contact lens material). The inventor believes that Benz 55G or Methafilcon A may be as good as, or better than, Ocufilecon B in the practice of the present invention, but no lenses according to the present invention have yet been made with these materials.

While the present invention has been disclosed in connection with the presently preferred embodiments described herein, it should be understood that there may be other embodiments which fall within the spirit and scope of the invention as defined by the claims. For example, this invention can be practiced with contact lenses that are made by any method now known or

1 hereafter invented, including (but not limited to)  
molding, spin casting, or extruding. This invention  
also can be applied to intraocular lens implants and  
refractive surgical procedures (including radial  
5 keratotomy, photo refractive keratotomy, and corneal  
implantation) that reshape the cornea. Furthermore,  
this invention can be practiced in combination with  
spherical or astigmatic (toric) contact lenses. Toric  
lens prescriptions comprise spherical power corrections,  
10 usually between +20 and -20 diopters (commonly between  
+8 and -8 diopters), and cylindrical power corrections,  
usually between .5 diopters and 10 diopters (commonly  
between 1 and 4 diopters). The present invention can be  
practiced within this entire range of toric (astigmatic)  
15 lens prescriptions. Accordingly, no limitations are to  
be implied or inferred in this invention except as  
specifically and explicitly set forth in the claims.

Industrial applicability. This invention can  
be used whenever it is desired to provide a contact lens  
20 that corrects for distance vision as well as near and  
intermediate vision.

25

30

35

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## CLAIMS

What is claimed is:

1. A contact lens, comprising:
  - 5 a circular central region overcorrected for near vision, wherein said central region is small enough to avoid impairing distance vision;  
at least one ring shaped transition region extending radially outward from said central region;
  - 10 a ring shaped outer region extending radially outward from said transition region corrected for distance vision; and  
a ring shaped carrier region extending radially outward from said outer region;
  - 15 wherein said transition region provides at least a partial diopter shift over said transition region between said overcorrection of said central region and said distance correction of said outer region.
2. A contact lens according to claim 1, wherein  
20 said central region is between approximately 1 millimeter and approximately 2.5 millimeters in diameter.
3. A contact lens according to claim 2, wherein  
25 said central region is between approximately 1.5 millimeters and approximately 1.9 millimeters.
4. A contact lens according to claim 1, wherein  
said central region has a diameter of less than approximately 1.9 millimeters.
5. A contact lens according to claim 2, wherein  
30 said central region has a diameter of approximately 1.5 millimeters.
6. A contact lens according to claim 2, wherein  
said central region has a diameter of approximately 1.9 millimeters.
- 35 7. A contact lens according to claim 1, wherein  
said central region is overcorrected for near vision by approximately 25% to approximately 100%.

1        8. A contact lens according to claim 1, wherein  
said lens has at least a first transition region and a  
second transition region.

5        9. A contact lens according to claim 8, wherein  
said lens has two transition regions and each of said  
transition regions is approximately .5 millimeters wide.

10       10. A contact lens according to claim 8, wherein  
said transition regions are aspherical.

10       11. A contact lens according to claim 8, wherein  
said transition regions are spherical.

15       12. A contact lens according to claim 8, wherein  
said diopter shift across said first transition region  
is at a first constant radial rate and said diopter  
shift across said second transition region is at a  
second constant radial rate.

20       13. A contact lens according to claim 8, wherein  
said first transition region provides a diopter shift of  
approximately 1.6 diopters, said second transition  
region provides a diopter shift of approximately 1.2  
diopters, and said outer region provides a diopter shift  
of approximately .9 diopters.

25       14. A contact lens according to claim 8, wherein  
said first transition region provides a diopter shift of  
approximately 1.1 diopters, said second transition  
region provides a diopter shift of approximately .8  
diopters, and said outer region provides a diopter shift  
of approximately .6 diopters.

30       15. A contact lens according to claim 1, wherein  
said outer region has a diameter of approximately 8  
millimeters.

35       16. A contact lens according to claim 1 wherein  
optical correction of at least one of said regions is  
provided by a material with differing indices of  
refraction in different portions.

35       17. A contact lens according to claim 1, wherein  
said lens is made from materials selected from the group  
consisting of conventional soft lens material, rigid gas

1 permeable contact lens material, or hard contact lens material.

18. An intraocular implant, comprising:

5 a circular central region overcorrected for near vision, wherein said central region is small enough to avoid impairing distance vision;

at least one ring shaped transition region extending radially outward from said central region;

10 a ring shaped outer region extending radially outward from said transition region corrected for distance vision; and

a carrier region extending radially outward from said outer region;

15 wherein said transition region provides at least a partial diopter shift over said transition region between said overcorrection of said central region and said distance correction of said outer region.

19. A refractive surgical procedure, comprising: shaping a human cornea to provide:

20 a circular central region overcorrected for near vision, wherein said central region is small enough to avoid impairing distance vision;

at least one ring shaped transition region extending radially outward from said central region;

25 a ring shaped outer region extending radially outward from said transition region corrected for distance vision;

30 wherein said transition region provides at least a partial diopter shift over said transition region between said overcorrection of said central region and said distance correction of said outer region.

20. A contact lens having a pupil area, comprising:

35 a central accommodation zone covering approximately half of said pupil area overcorrected for near vision by between approximately 25% to approximately 100%;

1       at least one concentric transition region extending  
radially outward from said accommodation region; and  
a concentric outer region extending radially outward  
from said transition region corrected for distance  
5 vision;

wherein said transition region provides at least a  
partial diopter shift over said transition region  
between said overcorrection of said central  
accommodation zone and said distance correction of said  
10 outer region.

21. A contact lens according to claim 20, having an  
add power of between approximately 3.5 and approximately  
3.9 diopters.

22. A contact lens according to claim 20, having an  
15 add power of approximately 3.7 diopters.

23. A contact lens according to claim 20, having an  
add power of between approximately 2 and approximately  
3.5 diopters.

24. A contact lens according to claim 20, having an  
20 add power of between approximately 2.4 and 2.8 diopters.

25. A contact lens according to claim 20, having an  
add power of approximately 2.6 diopters.

26. A process for aligning a central region of a  
contact lens, comprising:  
25 marking a centered spot on a diagnostic contact  
lens; and

detecting whether a user's pupils would be aligned  
with said central region.

27. A process according to claim 26, wherein said  
30 spot has a diameter of approximately 1.9 millimeters.

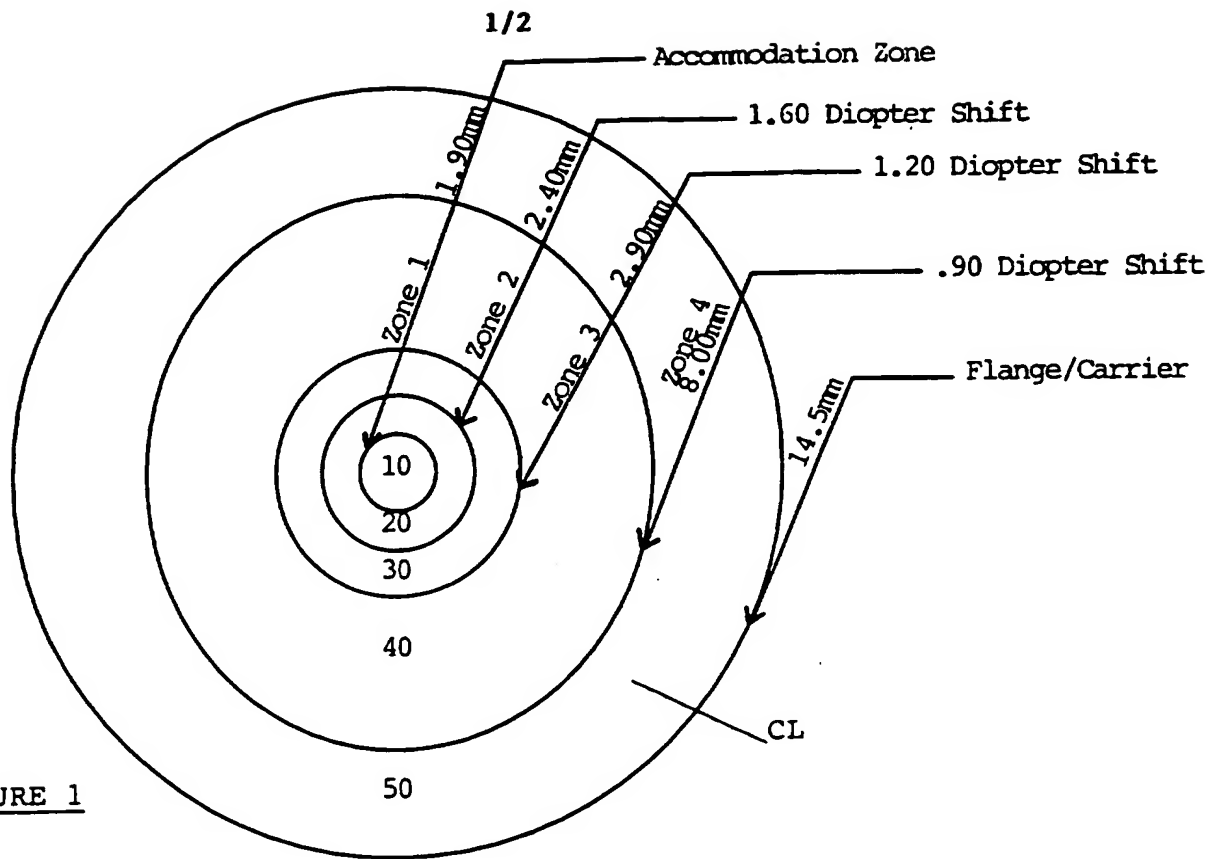


FIGURE 1

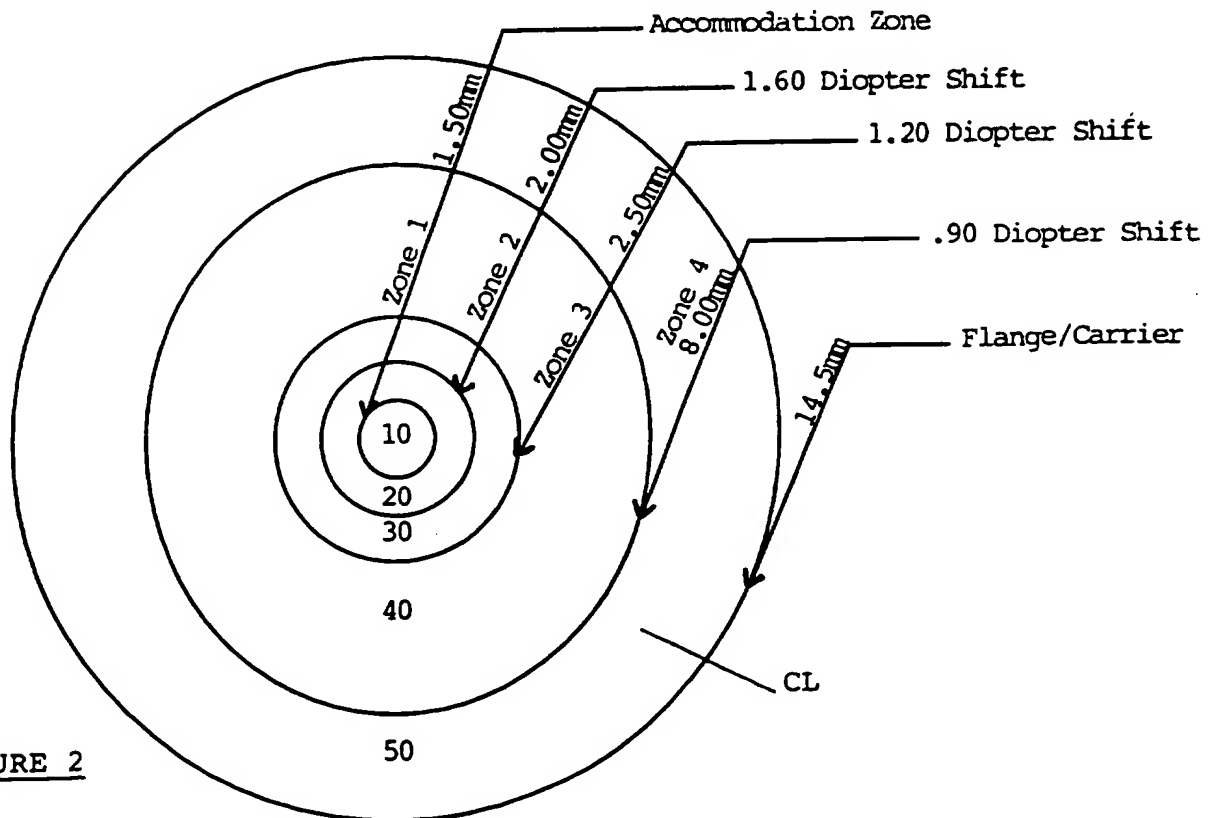


FIGURE 2

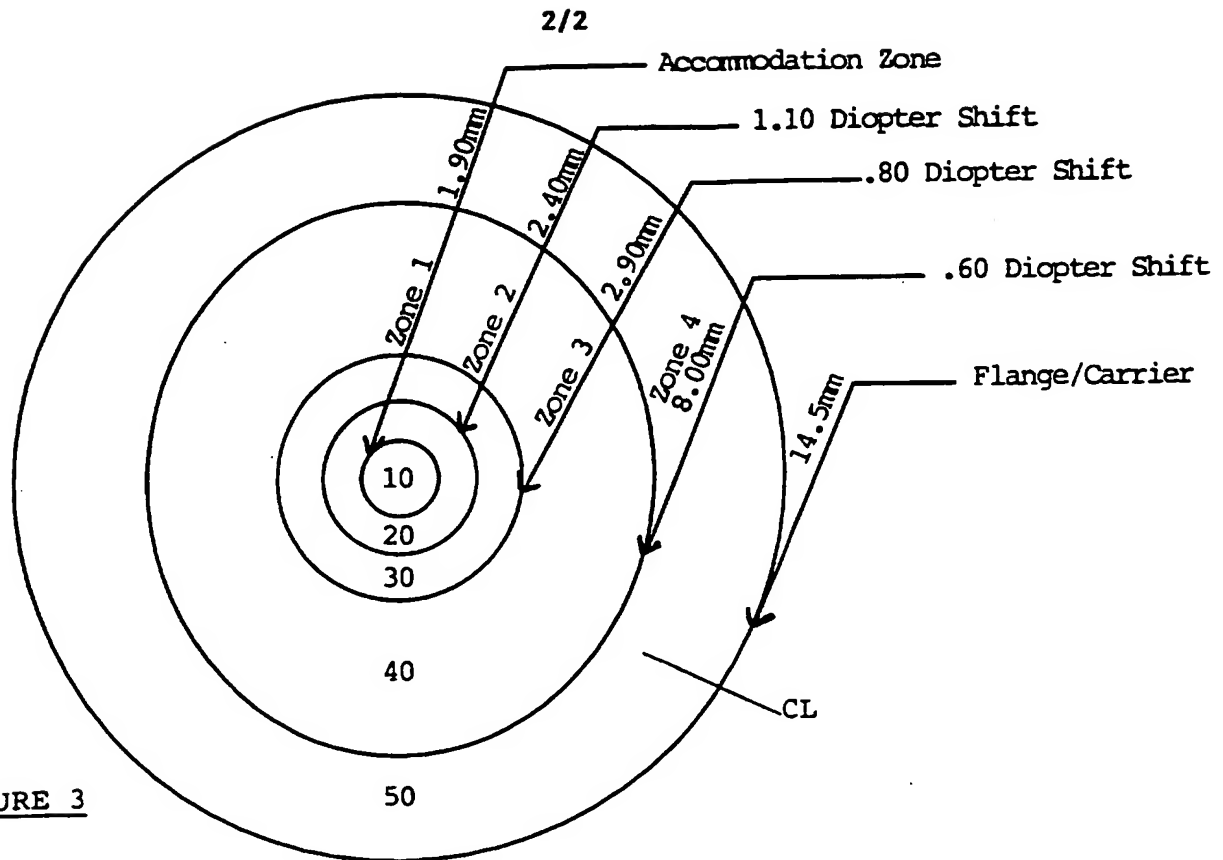


FIGURE 3

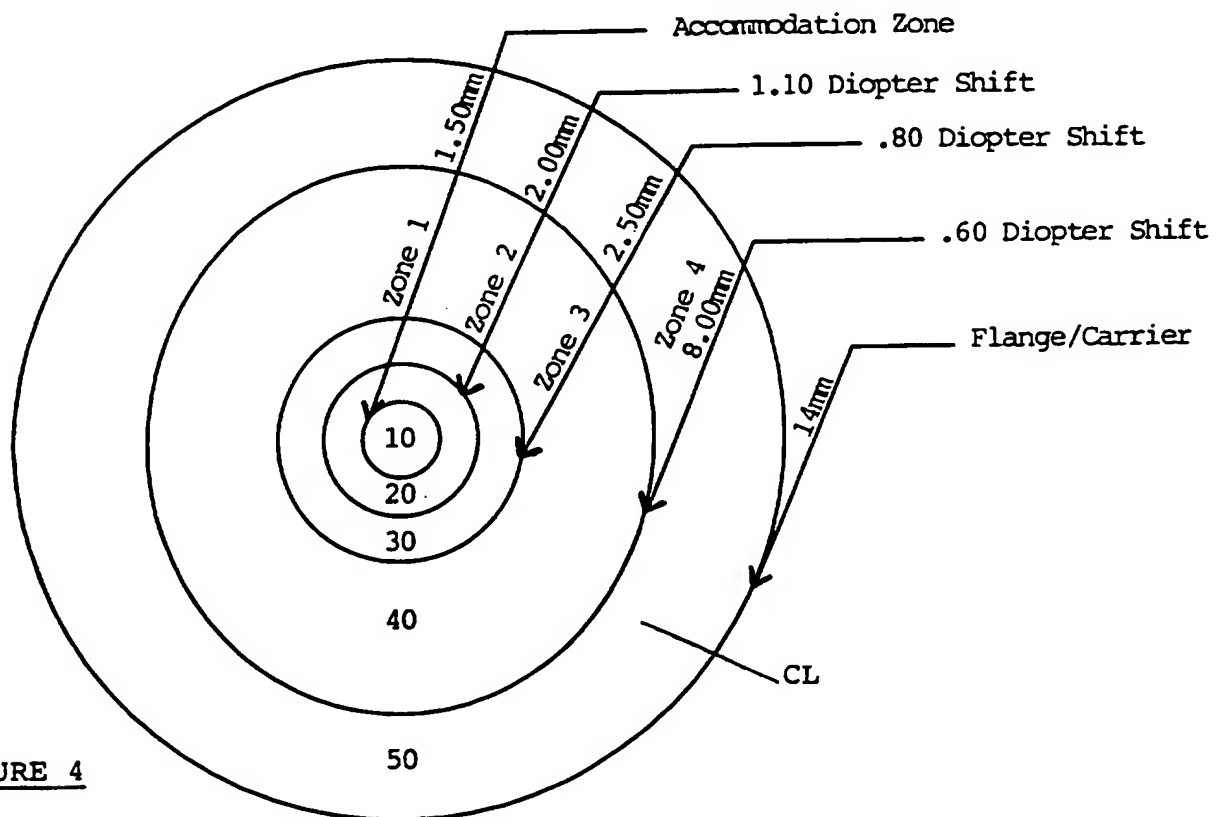


FIGURE 4

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/15589

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : G02C 7/02, 7/04; A61F 2/16; A61M 1/00

US CL : 351/161, 177; 623/6; 604/28

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 351/161, 177; 623/6; 604/28

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                    | Relevant to claim No. |
|-----------|---|-----------------------|
| X         | US 5,406,341 A (BLUM et al) 11 April 1995, Abstract, Figure 1   | 26-27                 |
| A         | US 4,869,587 A (BREGER) 26 September 1989, column 9, lines 25-62, column 4, lines 51-56, Figures 5-7. | 1-17, 20-25           |
| A         | US 5,158,572 A (NIELSON) 27 October 1992, column 2, line 42 to column 3, line 62, Figure 7.           | 1-25                  |

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

\* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document published on or after the international filing date

\*L\* document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

\*Z\* document member of the same patent family

Date of the actual completion of the international search

30 DECEMBER 1996

Date of mailing of the international search report

31 JAN 1997

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Authorized officer

JORDAN M. SCHWARTZ

Telephone No. (703) 308-0956

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

**BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING**

This ISA found multiple inventions as follows:

Group I, claim(s) 1-18 and 20-25, drawn to a lens providing multifocal optical correction (351/161;623/6).

Group II, claim(s) 19, drawn to a surgical procedure for reshaping the cornea (604/28).

Group III, claim(s) 26-27, drawn to a process for aligning the central region of a contact lens (351/177).

The inventions listed as Groups I, II and III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I invention is a lens providing optical correction; the special technical feature of the Group II invention is a surgical procedure for reshaping a human cornea; while the special technical feature of the Group III invention is a means of aligning a contact lens. Since the special technical feature of the Group I invention is not present in the Groups II and III claims, the special technical feature of the Group II invention is not present in the Groups I and III claims, and the special technical feature of the Group III invention is not present in the Groups I and II claims, unity is lacking.